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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/674,787

10/01/2003

Hidenobu Yaku

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3667

20277

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03/28/2006

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,787	YAKU ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on January 12, 2006 has been entered.

Status

2. Claims 1-12, 19-27 are pending. Claims 1-2, 7, and 19 are amended. Claims 13-18, 28-30 are withdrawn from consideration as being non-elected group. All arguments have been fully considered and thoroughly reviewed, and are deemed persuasive for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The amendment narrowed the scope of the invention by reciting "at least dATP or ddATP" and this action is made FINAL necessitated by amendment.

New Grounds of Rejections necessitated by Amendment

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-12, and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (USPN. 6,951,744) in view of Zhen et al. (J Biol. Chem., Vol. 272 (35), pp 22340-22348, 1997).

Clark et al. teach a method of claims 1-2, 8, and 19, of detecting an extension reaction and identifying a base at a target nucleic acid sequence (discriminating a base type) or detecting a base sequence of a target nucleic acid, wherein Clark et al. disclose that said method comprises

(a) preparing a sample solution containing a nucleic acid, a primer having a base sequence that is complementary to said target nucleic acid and at least a dATP or ddATP (col. 2, line 46-64, col. 45, line 14-19);

(b) allowing said sample solution to stand under conditions that cause said extension reaction and producing pyrophosphate (PPi) when said extension is caused (see col. 2, line 58-61, col. 45, line 16-19);

(c) bringing said sample solution into contact with a pyrophosphatase (PPase) enzyme (col. 5, line 1-30, col. 45, line 20-24);

(d and e) detecting said extension reaction based on the digestion of pyrophosphate salt by (PPase) (see col. 45, line 25-29).

With regard to claims 1-2, 5, and 19 Clark et al. et al also teach that said method detects extension products and identifies single base polymorphisms (base discrimination) and base sequence of the target nucleic acid (see col. 4, line 27-39).

With regard to claim 7, Clark et al. teach use of two different nucleotides to discriminate a base type (see col. 2, line 54-64).

With regard to claims 11, and 26, Clark et al. teach that the PPi release is measured as a primer extension product produced, which is detected electrically (see col. 11, line 31-49, Fig. 4, indicating gel electrophoresis);

With regard to claim 12, and 27, Clark et al. teach that said extension reaction is performed using polymerase chain reaction (PCR) (see col. 4, line 14-29)

However, Clark et al. did not specifically teach contacting sample solution with a permeable membrane having H^+ pyrophosphatase which hydrolyses pyrophosphate released during extension reaction and measuring the H^+ concentration either in solution on the front face of the membrane or in the solution at the back face of the membrane.

Zhen et al. teach a method for measuring pyrophosphate of claims 1-2, 3-4, 6, 8-10, 19-25, wherein Zhen et al. teach that said measuring includes the use of membrane associated H^+ pyrophosphatase and measuring the release of H^+ PPi concentration differences optically excitation and emission wavelengths of 495 and 540nm in pH gradient solutions (see page 22342, paragraph 2). With regard to claims 9-10, and 24-25, Zhen also teach the use of a pH sensitive pigment, acridine orange (page 22342, line 1-3 of paragraph 2).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of detecting extension product or base sequence based on PPi release as disclosed by Clark et al. with the step of including membrane associated H^+ pyrophosphatase to measure PPi release as disclosed by Zhen et al for the purpose of developing a sensitive method for stably detecting base extension reaction of a target nucleic acid. An ordinary person skill in the art would have been motivated to combine the method taught by the Clark et al. with the inclusion of membrane associated H^+ pyrophosphatase to

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achieve expected advantage of developing a sensitive method for detecting base sequence of a target nucleic acid. The ordinary artisan would have a reasonable expectation of success that the inclusion of said membrane associated H^+ pyrophosphatase would result in a sensitive measurement of PPi released during extension reaction because Zhen et al. explicitly taught the use of membrane associated H^+ pyrophosphatase in measuring the differences in PPi hydrolysis and H^+ translocation of mutant and wild type nucleic acid (see page 22340, col. 1, paragraph 1 (abstract or summary)) and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Response to arguments:

5. With regard to the objection made to the priority document, Applicants' arguments are fully considered and the objection is withdrawn in view of the persuasive arguments and no intervening art.
6. With regard to the objections to the drawings, Applicants' arguments and amendment to the drawings are fully considered and the objection is withdrawn herein in view of the amendment.
7. With regard to the objection to the specification, Applicants' arguments and amendment deleting embedded hyperlink or browser executable codes are fully considered and the objection is withdrawn herein in view of the amendment.
8. With regard to the objection to the title of specification, Applicants' arguments and amendment are fully considered and the objection is withdrawn herein in view of the amendment.

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9. With regard to the objection to the abstract of specification, Applicants' arguments and amendment are fully considered and the objection is withdrawn herein in view of the amendment.

10. with regard to the informalities noted in the specification, Applicants' arguments and amendment are fully considered and the amendment correcting the informalities are fully considered and the amendment has overcome the noted informalities.

11. With regard to the rejection of claims 112 and 19-27 under 35 USC 103(a) as being obvious over Nyren et al. in view of Zhen et al. , Applicants arguments and amendment reciting specific nucleotide as dATP or ddATP , are fully considered and the rejection is withdrawn herein in view of the amendment.

12. With regard to the rejection of claims 1-12, 19-27 under provisional obviousness-type double patenting, Applicants' submission of a terminal disclaimer is fully considered. However, it is noted that the terminal disclaimer is improper for referring to an incorrect serial No. of the co-pending reference application number. The rejection is maintained until a proper terminal disclaimer is submitted.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Examiner
Art Unit 1637


SURYAPRABHA CHUNDURU 3/20/06
PATENT EXAMINER